K120395

8.0 510(K) SUMMARY
Date Prepared: January 31, 2012

MAY 30 2012

8.1 SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By: John M. Lindskog
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8.2	Trade/Proprietary Name:	neria™ multi Subcutaneous Infusion Set
8.3	Common/Usual Name	Subcutaneous Infusion Set
8.4	Classification Name	Intravascular administration set
8.5	Classification	Class: II Panel: 80 Product Code: FPA Cite: 21 CFR 880.5440

8.6 Predicate Devices

The neria™ multi Subcutaneous Infusion Sets are substantially equivalent to the Unomedical Contact™ Subcutaneous Infusion Sets (K945617) and the MarCal Medical Sub Q Needle infusion set (K082818).

8.7 Indication for Use

The sets are indicated for the infusion of fluids into the body below the surface of the skin when attached to a fluid reservoir.

8.8 Intended Use

These neria™ multi sets are intended to be used by patients of all ages who have been prescribed subcutaneous infusion of immunoglobulin (IgG) for the treatment of Primary Immunodeficiency Disease (PID).

8.9 Product Description

The neria™ multi product is a multisite infusion catheter. The product has a luer lock connector that is designed to be attached to an infusion pump reservoir. The tubing from the luer connector is attached to a furcation or splitter block, which splits the fluid flow into two, three or four subcutaneous Infusion catheters. Each tube that exits the splitter terminates in a subcutaneous catheter with a stainless steel infusion needle set at 90 degrees from an adhesive pad.

The neria™ multi line will include three different needle lengths of 8, 10 and 12 mm. The product is provided with a separate tubing clamp or clamps to enable the user to selectively stop infusion to one or more sites as necessary. The sets are packaged in custom formed blisters sealed with a Sterikraft paper lid and sterilized in a validated EO gas cycle.

8.10 Technological Characteristics

The neria™ multi Subcutaneous Infusion Sets have the same technological characteristics as the current marketed products.

	neria™ multi	contact™	Sub Q Needle infusion set
CHARACTERISTICS			
DRUG COMPATIBILITY/THERAPY	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN)/PID	NONE SPECIFIED	NONE SPECIFIED
NUMBER OF CATHETERS/FURCATIONS	2, 3 AND 4	1 WITH NO FURCATIONS	1, 2, 3 AND 4
CLAMPS PROVIDED	1 OR 2	0	1, 2, 3, OR 4
NEEDLE MATERIAL	STAINLESS STEEL, AISI 304	STAINLESS STEEL, AISI 304	STAINLESS STEEL
NEEDLE LENGTHS	8, 10, 12 mm	6, 8, 10 mm	6, 9, 12, 14 mm
NEEDLE GAUGES	27	27 AND 29	24 AND 27
ANGLE OF INSERTION	90 DEGREES PERPENDICULAR	90 DEGREES PERPENDICULAR	90 DEGREES PERPENDICULAR
FIXATION TO SKIN	ADHESIVE PAD	ADHESIVE PAD	ADHESIVE "BUTTERFLY"
MATERIALS COMPONENTS	SAME AS CONTACT™	SAME AS NERIA™ MULTI	UNKNOWN
STERILIZATION METHOD	ETO	ETO	GAMMA RADIATION

8.11 Performance Data

The devices were tested for the following attributes and conform to all pre-defined criteria.

- 8.11.1 Dimensional Tests
- 8.11.2 Needle length
- 8.11.3 Tubing Length
- 8.11.4 Functional Tests
- 8.11.5 Leak test
- 8.11.6 Flow test
- 8.11.7 Pull (Tension) tests
  - 8.11.7.1 Furcator – tubing
  - 8.11.7.2 Set base – tubing
  - 8.11.7.3 Luer – tubing
  - 8.11.7.4 Set base - adhesive
- 8.11.8 Biological Tests
  - 8.11.8.1 Biocompatibility Test - meet the requirements of ISO 10993-1, Biological evaluation of Medical Devices.
- 8.11.9 Chemical Testing
  - 8.11.9.1 Drug/Device compatibility test – the sets were tested for Drug compatibility with Hizentra®, Immune Globulin Subcutaneous (Human), 20% Liquid, manufactured by CSL Behring

8.12 Conclusion

Unomedical concludes based on the information presented that the new product is substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Unomedical A/S
C/O Lee H. Leichter MBA, RAC
President
P/L Biomedical
10882 Stonington Avenue
Fort Myers, Florida 33913-8414

MAY 30 2012

Re: K120395
Trade/Device Name: neria™ multi Subcutaneous Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 10, 2012
Received: May 15, 2012

Dear Mr. Leichter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

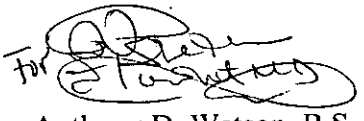
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (If Known):

Device Name: neria™ multi infusion set

Indications for Use: The sets are intended for the infusion of fluids into the body below the surface of the skin when attached to a fluid reservoir.

Prescription Use __√__ AND/OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/24/12

)ivision Sign-Off)
ıvision of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K120895